U.S. FOOD & DRUG ADMINISTRATION

April 29, 2019

In Response Refer to File: ***2019-2114***

Dan Vergano
BuzzFeed News
[redacted]
Washington, DC 20009

Dear Requester,

This is in response to your Freedom of Information Act request dated March 7, 2019, in which you requested a copy of all public records of requests for exemptions from mandatory reporting requirements to the FDA Adverse Event Reporting System (FAERS) and the Human Cell & Tissue Products (HCT/P) Adverse Reaction Reporting System. Your request was received in the Center for Drug Evaluation and Research (CDER) on April 17, 2019.

A search of the records of the Center for Drug Evaluation Research did not locate any record responsive to your request. The Office of Surveillance and Epidemiology (OSE) confirmed the result.

This concludes the response for the Center for Drug Evaluation and Research. Please note that another office within the FDA will also be providing a response to this request. If we can be of further assistance to you, please do not hesitate to contact Diderot Nicolas at [redacted].

Sincerely,

Guruprasad S. Udapi -S
Digitally signed by Guruprasad S. Udapi -S
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Date: 2019.04.29 17:26:04 -04'00'

Guruprasad Udapi
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Center for Drug Evaluation and Research